HOUSE BILL No. 1184

DIGEST OF INTRODUCED BILL

Citations Affected: IC 16-18-2; IC 16-42-26; IC 16-46-18; IC 25-22.5-1-2.1.

Synopsis: Breakthrough therapies. Establishes the breakthrough therapies research fund. Provides that a drug, biological product, or medical device that has been designated as a breakthrough therapy under federal law may be made available to a qualified patient and offered by a physician as a part of the patient's medical treatment. Specifies that a civil or criminal cause of action is not created against a manufacturer or health care provider for any harm to a qualified patient resulting from use of an investigational drug, biological product, or device.

Effective: July 1, 2024.

Moed

January 9, 2024, read first time and referred to Committee on Public Health.

Introduced

Second Regular Session of the 123rd General Assembly (2024)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type.~~

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~*this style type*~~ reconciles conflicts between statutes enacted by the 2023 Regular Session of the General Assembly.

HOUSE BILL No. 1184

A BILL FOR AN ACT to amend the Indiana Code concerning health.

Be it enacted by the General Assembly of the State of Indiana:

SECTION 1. IC 16-18-2-39.5 IS ADDED TO THE INDIANA CODE AS A **NEW** SECTION TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2024]: **Sec. 39.5. "Breakthrough therapy", for purposes of IC 16-46-18, has the meaning set forth in IC 16-46-18-1.**

SECTION 2. IC 16-18-2-143, AS AMENDED BY P.L.1-2010, SECTION 69, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2024]: Sec. 143. (a) "Fund", for purposes of IC 16-26-2, has the meaning set forth in IC 16-26-2-2.

(b) "Fund", for purposes of IC 16-31-8.5, has the meaning set forth in IC 16-31-8.5-2.

(c) "Fund", for purposes of IC 16-41-39.4, refers to the childhood lead poisoning prevention fund established by IC 16-41-39.4-3.1.

(d) "Fund", for purposes of IC 16-41-39.8, refers to the lead trust fund established by IC 16-41-39.8-7.

(e) "Fund", for purposes of IC 16-46-5, has the meaning set forth in IC 16-46-5-3.

(f) "Fund", for purposes of IC 16-46-12, has the meaning set forth in IC 16-46-12-1.

(g) "Fund", for purposes of IC 16-41-42.2, has the meaning set forth in IC 16-41-42.2-2.

(h) "Fund", for purposes of IC 16-35-8, has the meaning set forth in IC 16-35-8-2.

(i) "Fund", for purposes of IC 16-46-18, has the meaning set forth in IC 16-46-18-2.

SECTION 3. IC 16-42-26-2, AS ADDED BY P.L.2-2015, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2024]: Sec. 2. As used in this chapter, "investigational drug, biological product, or device" means an investigational or experimental

~~(1)~~ drug,

~~(2)~~ biological product, or

~~(3)~~ medical device

that has:

(1) successfully completed Phase I of a federal Food and Drug Administration approved clinical trial, but has not been approved for general use by the federal Food and Drug Administration and remains under investigation in a clinical trial; **or**

(2) been designated as a breakthrough therapy under 21 U.S.C. 356(a) of the federal Food, Drug, and Cosmetic Act.

SECTION 4. IC 16-42-26-5, AS ADDED BY P.L.2-2015, SECTION 3, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2024]: Sec. 5. This chapter does not create a **civil or criminal** cause of action against a manufacturer of an investigational drug, biological product, or device for any harm to a qualified patient resulting from use of an investigational drug, biological product, or device.

SECTION 5. IC 16-46-18 IS ADDED TO THE INDIANA CODE AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2024]:

Chapter 18. Breakthrough Therapies Research Fund

Sec. 1. As used in this chapter, "breakthrough therapy" refers to a drug, biological product, or medical device that has been designated as a breakthrough therapy under 21 U.S.C. 356(a) of the federal Food, Drug, and Cosmetic Act.

Sec. 2. As used in this chapter, "fund" refers to the breakthrough therapies research fund established by section 3 of this chapter.

Sec. 3. The breakthrough therapies research fund is established for the purpose of providing financial assistance to research

institutions in Indiana to study breakthrough therapies to treat serious mental illness.

Sec. 4. (a) The fund shall be administered by the state department.

(b) The expenses of administering the fund shall be paid from money in the fund.

Sec. 5. (a) The fund consists of the following:

(1) Appropriations from the general assembly.

(2) Donations to the fund.

(3) Gifts to the fund.

(b) The treasurer of state shall invest the money in the fund not currently needed to meet the obligations of the fund in the same manner as other public money may be invested. Interest that accrues from these investments shall be deposited in the fund.

(c) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

SECTION 6. IC 25-22.5-1-2.1, AS AMENDED BY P.L.2-2015, SECTION 4, IS AMENDED TO READ AS FOLLOWS [EFFECTIVE JULY 1, 2024]: Sec. 2.1. (a) An individual who consents under IC 34-18-12 may receive any experimental or nonconventional medical treatment if:

(1) a licensed physician has personally examined the individual and agrees to treat the individual;

(2) the treating physician determines:

(A) there is no reasonable basis to conclude that the medical treatment, when administered as directed, poses an unreasonable and significant risk of danger to the individual receiving the medical treatment; or

(B) the:

(i) individual has been diagnosed with a terminal disease or condition and does not have comparable or satisfactory treatment options that are approved by the federal Food and Drug Administration and that are available to diagnose, monitor, or treat the individual's disease or condition; and

(ii) probable risk to the individual from the experimental or nonconventional medical treatment is not greater than the probable risk from the individual's disease or condition; and

(3) the treating physician has provided the individual with a written statement and an oral explanation of the medical treatment that the individual has acknowledged by the individual's signature or the signature of the individual's legal representative and that discloses the following:

(A) That the medical treatment is experimental or nonconventional.

(B) That the investigational drug, biological product, or device (as defined in IC 16-42-26-2) has not been approved by the federal Food and Drug Administration for any indication.

(C) The material risks generally recognized by a reasonably prudent physician of the medical treatment's side effects.

(D) An explanation of the medical treatment, including expected frequency and duration of the treatment.

(b) If the medical treatment is to be provided on an inpatient or outpatient basis at a hospital licensed under IC 16-21, then that type of treatment must have been approved by the governing board of the hospital or by a committee of the hospital authorized by the governing board to approve the types of experimental or nonconventional medical treatments that may be provided at the hospital on an inpatient or outpatient basis.

(c) The medical licensing board shall develop protocols for medical treatments that are provided in a setting other than the inpatient or outpatient hospital setting specified in subsection (b). A physician who fails to comply with a protocol developed under this subsection shall be subject to discipline by the medical licensing board.

(d) This section does not require any person or organization to provide an individual with access to a medical treatment not otherwise commercially available to that individual.

(e) This section does not require:

(1) an insurer;

(2) a fraternal benefit society;

(3) a nonprofit corporation;

(4) a health maintenance organization (as defined in IC 27-13-1-19);

(5) a preferred provider arrangement under IC 27-8-11; or

(6) a limited service health maintenance organization (as defined in IC 27-13-34-4);

to provide coverage or make payment beyond the terms and conditions of the contract for medical treatment authorized under this section.

(f) This section does not create a **civil or criminal** cause of action against a health care provider involved in connection with the use of an investigational drug, biological product, or device by a patient for any harm to the patient from the investigational drug, biological product, or device.

(g) An experimental medical treatment under this section may include a:

(1) drug;

(2) biological product; or

(3) medical device;

that has been designated as a breakthrough therapy under 21 U.S.C. 356(a) of the federal Food, Drug, and Cosmetic Act.